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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,827	02/23/2004	Audrey VanStockum	SNH 3001	5450

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KRAMER & AMADO, P.C.
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Alexandria, VA 22314

EXAMINER

ARNOLD, ERNST V

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/782,827

Applicant(s)

VANSTOCKUM, AUDREY

Examiner

Ernst V. Arnold

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-17 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-17 and 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7, 9-17 and 19-25 are pending.

The Examiner acknowledges Applicant's remarks filed on 11/20/06. Applicant's arguments have been carefully considered. Applicant's amendments have necessitated a new ground of rejection. This Action is FINAL.

Applicant has submitted a new abstract.

Withdrawn rejections:

Claims 1-17 and 19-22 were rejected under 35 U.S.C. 112, first paragraph. Applicant has submitted a declaration under 37 CFR 1.132 and has amended the claims to read on a method of treating vitiligo and grey hair and a method of restoring pigmentation of skin or hair. Applicant has demonstrated some results for the method and the Examiner is withdrawing the rejection.

Claim 20 was rejected under 35 U.S.C. 112, second paragraph. Applicant has amended the claims and the Examiner is withdrawing the rejection.

Claims 1-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Montes (US 4,985,443) in view of Ortonne et al. (Vitiligo and Other Hypomelanoses of Hair and Skin, 1983), Kolyadenko et al. (International Journal of Artificial Organs 2000, 23(8), 568) and Kelly (Alternative Medicine Review 1997, 2(2), pages 116-127). Applicant asserted that Montes teaches intramuscular injection of vitamin B12 and not

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the instantly claimed oral administration. The Examiner finds this persuasive and withdraws the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 recites the limitation "said female patient" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim. Claims 13-15 are rejected as being indefinite because they are dependent on an indefinite base claim. Correction is required. The Examiner will examine the claim as it reads on any patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-7, 9-17 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson (US 6,149,933) in view of Montes (US 4,985,443), Kolyadenko et al. (International Journal of Artificial Organs 2000, 23(8), 568) and Randic et al. (Biology of Reproduction 1973, 8, 495-498).

Applicant claims a method of treating vitiligo or grey hair and methods of restoring pigmentation of skin or hair in a human patient in need thereof.

Determination of the scope and content of the prior art
(MPEP 2141.01)

Nelson teaches methods of suppressing or reversing gray of hair and pigment restoration (Abstract and claims 9 and 21). Neslon teaches a method comprising a dietary supplement in the form of a tablet for oral administration with 38.4 mg copper per day, pyridoxine HCl (a hydrochloride salt) of 3 mg per day, zinc in the form of zinc oxide of 15 mg per day, calcium pantothenate of 819 mg per day (Column 4, lines 5-8 and Column 6, example 6). Nelson suggests the addition of other B-complex vitamins (Column 3, lines 50-52).

Montes teaches methods of treating vitiligo, a skin hypopigmentation disorder, with subcutaneous injection of vitamin B12 of 1 mg per month, and oral administration of vitamin C of 500 mg per day and folic acid of 2-50 mg per day (Column 4, line 48, line 68-column 5, line 3 and claim 1).

Kolyadenko et al. teach the application of copper and zinc containing adsorbents to the skin followed by UV irradiation in vitiligo treatment. It is the Examiner's position that the topical application teaching of Kolyadenko et al. suggests skin creams/lotions.

Randic et al. teaches variation in the copper levels in cervical mucosa during normal menstrual cycles and lowered copper levels in cervical mucosa during the fertile phase might be important in permitting optimum sperm survival and transport (page 498, left column).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

1. Nelson does not expressly teach adding vitamin B12 or folic acid, vitamin B9, in their methods.
2. Nelson does not expressly teach subcutaneously administering vitamin B12.
3. Nelson does not expressly teach a method of restoring pigmentation of skin or hair in the absence of copper on days when the female patient is undergoing menses.
4. Nelson does not expressly teach a method of restoring pigmentation of the skin or hair where the components are compounded into a topically applied formulation.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add vitamin B12 and folic acid, as suggested by Montes, to the composition and method of Nelson and produce the instant invention.

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One of ordinary skill in the art would have been motivated to do this because: 1) Nelson suggests adding other B-complex vitamins and 2) "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). One of ordinary skill in the art can easily calculate that a month dose of 1 mg vitamin B12, as taught by Montes, calculates to about 0.03 mg per day and could have formulated that amount of vitamin B12 into the dietary supplement of Nelson. It is the Examiner's position that if the tablet of Nelson finds its way under the tongue then that is sublingual administration.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made subcutaneously administer vitamin B12, as suggested by Montes, to the composition and method of Nelson and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Montes teaches this route of administration.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to leave copper out of a method of restoring pigmentation of skin or hair in a female patient during menses and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Randic et al. teaches variation in copper levels during the ovulatory cycle and one

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would want to keep copper low in anticipation of the ovulation phase to maximize the chance of fertilization.

4. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to compound the components of Nelson into a topically applied formula, as taught by Kolyadenko et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Kolyadenko et al. teach that this is an appropriate means of treating skin pigmentation disorders.

Please note that simply walking outside exposes one to the sun and UV radiation.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

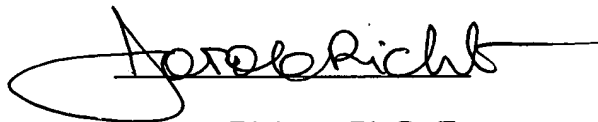
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
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A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning and a horizontal line extending to the right.

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600